

REMARKS

The allowance of Claims 3-4, 6-9, 11, 15-16, and 20-22 is gratefully acknowledged.

Claims 1-2, 5, 10, 13-14 and 17-18 were rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. 5,269,301 (Cohen). Amended Claim 1 describes an atrial defibrillator, comprising a portable, non-implantable housing; a pair of defibrillator pads operable to be applied to the outside of a patient's body; an operator verifier for determining operator authorization; a shock generator disposed in the housing, coupled to the pads, and operable to shock the patient via the pads in response to a shock command from an authorized operator; and an analyzer disposed in the housing and operable to receive a cardiac signal from the patient, to determine from the signal whether the patient is experiencing atrial fibrillation, and to enable the shock generator if the patient is experiencing atrial fibrillation. An embodiment of the defibrillator of Claim 1 is ideal for home use by the patient and laypersons because of the safety provision of an operator verifier which determines operator authorization. In most cases a friend or relative of a patient will operate the defibrillator to treat AF due to the possibility of the patient becoming unconscious. In that case the operator verifier will verify the presence of an operator other than the patient. But for some treatment regimens the patient may be allowed to treat himself/herself, in which case the operator verifier will recognize the patient as the authorized operator. Home treatment for AF can then proceed safely and conveniently without the need for a hospital visit.

The Cohen patent describes a multi-functional hospital monitoring and treatment instrument of the type referred to on page 2 of the present application. Such instruments are commercially available, an example of which is the Philips MRX monitor/defibrillator. These instruments are capable of monitoring a wide range of patient parameters such as heartbeat, blood pressure, blood oxygen, CO2, and others as listed in column 6 of the Cohen patent. As Cohen states at column 4, lines 34-36 of this patent, these instruments are designed for use in emergency rooms or critical care units under direction of a trained clinician or physician. See column 7 of Cohen at lines 30 and 43, column 8 at lines 27-28 and column 9 at lines 5-6 and 11-12. These instruments are

far too complex to be operated by patients or laypersons at home. Since they are only used in clinics and hospitals under clinician or physician direction, there is no need to verify the authorization of an operator, for they are always operated by medical professionals. And indeed, Cohen provides for no operator verification in his instrument. Consequently it is respectfully submitted that amended Claim 1 and its dependent Claims 2, 5, and 10 cannot be anticipated by Cohen.

Amended Claim 13 describes a nonsurgical method of treating atrial fibrillation, comprising transdermally receiving a cardiac signal from a patient by a transdermal electrode; determining from the signal with a portable external analyzer whether the patient is experiencing atrial fibrillation; determining the presence of an authorized operator; enabling a portable shock generator with a signal from the portable analyzer; receiving a shock command from an authorized operator; and shocking the patient with the portable shock generator by means of the transdermal electrode in response to the shock command if the patient is experiencing atrial fibrillation. This method includes the step of determining the presence of an authorized operator which, as stated above, the Cohen instrument cannot do. The shock command in the inventive method is then received from an authorized operator. Accordingly it is respectfully submitted that Cohen cannot anticipate amended Claim 13 or its dependent Claim 18:

Claim 14 describes a nonsurgical method of treating atrial fibrillation, comprising receiving a cardiac signal from a patient; determining from the signal with a portable external analyzer whether the patient is experiencing atrial fibrillation; informing the patient by means of the analyzer that the patient is experiencing atrial fibrillation; receiving a shock command from an operator; and shocking the patient with a portable shock generator in response to the shock command if the patient is experiencing atrial fibrillation, further comprising: applying defibrillator pads to the patient; wherein the receiving comprises receiving the cardiac signal via the pads, and wherein the shocking comprises shocking the patient via the pads. The rejection of this claim contends that the patient is informed that he/she is experiencing atrial fibrillation by the display 9 of the Cohen instrument. However as previously mentioned the Cohen

instrument is designed entirely for operation and use by trained medical professionals. A close reading of the description of the display 9 shows that it is a diagnosis display (col. 7, lines 32-52). This display displays a diagnosis for "the person in charge," who is certainly not the patient. The "attending clinician or physician" then must concur with the diagnosis before treatment is delivered to the patient. It is clear that this display 9, like the rest of the instrument, is strictly for medical professionals. There is no hint in Cohen that the patient is to have any access to display 9, including any indication from the instrument that he/she is experiencing AF. Accordingly it is respectfully submitted that Cohen does not anticipate Claim 14.

Amended Claim 17 describes a nonsurgical method of treating atrial fibrillation, comprising transdermally receiving a cardiac signal from a patient; determining from the signal whether the patient is experiencing atrial fibrillation; verifying the presence of an authorized operator; applying a shock enable signal to a portable shock generator if the patient is experiencing atrial fibrillation; shocking the patient with the portable shock generator external to the patient if the patient is experiencing atrial fibrillation and an authorized operator is present; and wherein the determining comprises determining the patient's heart rate and determining that the patient is not in atrial fibrillation if the heart rate is outside of a predetermined range. As mentioned above, Cohen has no ability to verify the presence of an authorized operator, nor for seeing that the patient is shocked if an authorized operator is present. The Cohen instrument is designed for the clinic or hospital and has no need for such a provision. Accordingly it is respectfully submitted that Cohen cannot anticipate amended Claim 17.

Claims 12 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cohen and US Pat. 3,442,269 (Druz). Druz describes a cardioscope which is to be operated by trained medical professionals. Like Cohen, there is no need to determine operator authorization for the Druz cardioscope. Thus it is respectfully submitted that the combination of Cohen and Druz cannot render Claim 1 unpatentable nor its dependent Claim 12. Claim 19 depends from Claim 13 which includes the step of determining the presence of an authorized

operator, not found in Cohen or Druz. Accordingly it is respectfully submitted that Claim 19 is patentable over Cohen and Druz.

Amended Claim 23 describes an atrial defibrillator comprising a portable, non-implantable housing; a pair of defibrillator pads operable to be applied to the outside of a patient's body; a shock control operable to allow a patient to defer a self-administered shock; a shock generator disposed in the housing and responsive to the shock control, coupled to the pads, and operable to shock the patient via the pads with a multi-phasic waveform; and an analyzer disposed in the housing and operable to receive a cardiac signal from the patient, to determine from the signal whether the patient is experiencing atrial fibrillation, and to enable the shock generator if the patient is experiencing atrial fibrillation. The Cohen and Ramsey III instruments are to be operated only by medical professionals. The esophageal catheter of Ramsey III is not to be used at home or self-administered. It follows that neither provides a shock control which is operable to allow a patient to defer a self-administered shock. As indicated on pages 3 and 5 of the present application, such a control enables a patient to treat AF with a self-administered shock at a time and place of his/her own choosing, avoiding embarrassment at work and social functions. Those are not considerations for Cohen and Ramsey III, whose instruments are only designed for use in medical facilities by trained professionals. For these reasons it is respectfully submitted that amended Claim 23 is patentable over Cohen and Druz.

In view of the foregoing amendment and remarks it is respectfully submitted that Claims 1, 2, 5, 10, 13, 14, 17, and 18 above are not anticipated by Cohen and that Claims 12, 19, and 23 presented above are patentable over any combination of Cohen, Druz and Ramsey III. Accordingly it is respectfully requested that the rejection of Claims 1, 2, 5, 10, 13, 14, 17, and 18 under 35 U.S.C. §102(b) and of Claim 12, 19 and 23 under 35 U.S.C. §103(a) be withdrawn.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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